

Rejuvenate^{Plus}TM Efficacy Study

Participant Informational Piece



Rejuvenate^{Plus}TM is a new dietary supplement created for dogs with mobility problems. It is a next generation creatine product that replenishes your dog's cellular stores of creatine. Our research indicates that increasing cellular levels of creatine with Rejuvenate^{Plus}TM has anti-inflammatory effects in addition to providing a natural restoration and healing of soft tissue (muscle and joint). Our open label study performed at Heartland Animal Hospital under the direction of Dr. Andrew Kliewer, DVM indicated that Rejuvenate^{Plus}TM was both safe and effective. Of the eighteen dogs enrolled in the study, 17 reported a positive improvement in the mobility of the dog following Rejuvenate^{Plus}TM (94% response rate). Furthermore, the anti-inflammatory and restorative effects of Rejuvenate^{Plus}TM occurred rapidly (i.e. within days). For more details regarding our open label study of Rejuvenate^{Plus}TM, you are encouraged to visit our website at www.rejuvenateplus.ca.

We are currently interested in identifying dogs with joint and mobility problems for conducting a double-blind efficacy study of our product. As a participant in our double-blind study examining the effects of Rejuvenate^{Plus}TM you will receive a 14-day supply of either Rejuvenate^{Plus}TM, or placebo (capsule containing no active ingredients). The study will consist of an initial assessment to be performed by your own veterinary. At this initial assessment, the veterinary will X-ray the joint of concern (if there is not a recent X-ray already on file), take a blood sample, and perform a clinical assessment of the severity of the affected joint. Following the initial assessment, the veterinary staff will provide you with a 2-week supply of either Rejuvenate^{Plus}TM or placebo and instruct you as to the necessary dose and dosing schedule. The veterinary staff will also provide you with a pedometer and an activity log to monitor your dog's activity. If a pre-assessment survey of your dog's mobility and function has not already been completed, the veterinary staff will assist you with the survey at this time. After a 7-day period of mobility/activity assessment with the pedometer, you will be instructed by the veterinary staff to begin treatment. After one week of treatment, you will fill out the Midway-Treatment Survey which is included in this packet. At the end of two-week treatment, you will fill out the Post-Treatment Survey which is included in this packet and your dog will be scheduled for a post-trial examination with your veterinarian. In addition to a clinical assessment, the veterinarian will obtain a final blood sample from your dog, and collect any remaining product, as well as any activity logs or owner surveys that have not already been returned.

The total duration of the trial is 3-weeks (1 week for obtaining pre-treatment baseline values and two-weeks of treatment). Those owner's whose dogs are selected to participate in the trial will be provided the pre and post clinical assessment and all materials associated with the study at no cost. In addition, owners will receive \$100 upon completion of the study. The raw material and finished product your dog will be taking as a participant in the study is manufactured and prepared by Vireo Resources LLC, under the same Good Manufacturing Practices (GMP) required for pharmaceutical agents used for human consumption. In order to scientifically evaluate the response to Rejuvenate^{Plus}TM, neither your veterinary nor you know which treatment your dog has received until the conclusion of the study. Regardless of the treatment group you were in, every study participant will receive a free bottle of Rejuvenate^{Plus}TM upon completion of the study. Thank you for your interest in our product, we look forward to your participation in this important study.

Synopsis of Study:

Initiated November 2009 – Estimated Conclusion date March 1, 2010

Study involves 18 dogs (9 in the RejuvenatePlus treatment group and 9 receiving Placebo) with confirmed clinical documentation of Osteoarthritis (OA) enrolled from 3 separate private practice veterinary clinics in the Midwest United States. The clinical sites and veterinaries responsible at each site are listed below.

Each dog underwent pretrial selection process to confirm OA (radiograph of inflicted joint), as well as owner survey to establish baseline pain and mobility problem (see attached Pain and Mobility Score Sheet). Dogs with confirmed OA and pain and mobility index scores of 22 or higher were enrolled in 2 week double blind trial. Mobility of each dog was monitored for one week prior to initiation of the study using pedometers attached to the collar of the dog to establish baseline mobility. Dogs were treated for two weeks with either placebo or RejuvenatePlus. During this two week period, owners were asked to record pedometer readings on a daily basis. Owners were also asked to assess pain and mobility after one week of treatment and at the conclusion of the two week study. The pain and mobility assessment was exactly the same as used in the pretrial selection process.

Data obtained include:

- 1) pre and post trial blood samples for each dog to evaluate blood chemistry profiles and identify alterations in pro-inflammatory blood markers
- 2) pain and mobility assessments for each dog from pretrial and 2 week trial period to identify owner perceptions of pain and mobility of their dog during study compared to pretrial baseline
- 3) pedometer readings from one week pretrial period and 2 week trial period to determine actual mobility of dog during trial period compared to the pretrial baseline data

Clinics Participating in Study:

Animal Medical Clinic North 10312 N. Second St Machesney Park IL; Dr A. Guarino-Herbik

Animal Medical Group 3316 North 120th Street, Omaha NE; Dr R. Van Horn

Richmond Veterinary Clinic 9902 Main Street Richmond IL; Dr K. Brand

Interim Report:

The dogs on the active ingredients show a significant double digit improvement in the number of steps recorded by the pedometer reading during the two week trial period. The dogs on the placebo showed no significant difference in pedometer readings during the two week trial period. Both groups were compared to their own one week pre-treatment baseline results.

The dogs on the active ingredients had a significant double digit reduction in their pain and mobility assessments scores compare to the assessments scores of the placebo group of dogs.

The testing of the blood chemistry profiles and pro-inflammatory markers is currently being done.

Specific data will not be release until the study has been published in a peer reviewed Veterinarian Journal.

February 2010

Rejuvenate^{Plus} Double Blind Trial in OA Dogs